

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

Sandoz Inc. and RareGen, LLC

Plaintiffs,

v.

United Therapeutics Corporation and
Smiths Medical ASD, Inc.

Defendants.

Civil Action No. 3:19-cv-10170-
BRM-LHG

SMITHS MEDICAL ASD, INC.'S ANSWER TO COMPLAINT

INTRODUCTION

Defendant Smiths Medical ASD, Inc. (“Smiths”) sets forth the following for its Answer and Affirmative Defenses to the Complaint filed in the above-captioned action by Sandoz, Inc. (“Sandoz”) and Raregen, LLC (“Raregen”). All responses are based solely on the knowledge and information of Smiths. Unless otherwise stated, Smiths does not purport to admit or characterize the conduct of any other defendant. To the extent the headings in the Complaint contain factual allegations to which a response is required, they are denied. All other allegations not specifically admitted are denied. Smiths reserves the right to amend its Answer, in whole or in part.

1. Smiths denies the allegations in paragraph 1.
2. Smiths admits that PAH is a life-threatening disease that causes high blood pressure in the arteries that run from the heart to the lungs. Smiths admits that some PAH patients do use infusion pumps to administer treprostinil, some of which are manufactured by Smiths. Smiths also admits it manufactures single-use cartridges that are specifically designed for the CADD MS 3 pump but denies the remaining allegations in this paragraph.

3. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 3, and accordingly denies all such allegations.

4. Smiths denies the allegations in paragraph 4.

5. The allegations in paragraph 5 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 5.

6. The first and last sentences of Paragraph 6 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies those allegations. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 6, and accordingly denies all such additional allegations.

7. Smiths admits that Sandoz and Raregen have brought this action under federal and state law, but denies the remainder of the allegations in paragraph 7.

THE PARTIES

8. Smiths admits that Sandoz sells generic medicines. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining

allegations contained in paragraph 8, and accordingly denies all such additional allegations.

9. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 9, and accordingly denies all such allegations.

10. Smiths admits that United Therapeutics makes Remodulin, Tyvaso, Orenitram and Adcirca. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 10, and accordingly denies all such allegations.

11. Smiths admits the allegations in paragraph 11.

JURISDICTION AND VENUE

12. The allegations in the first sentence of Paragraph 12 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in the first sentence of Paragraph 12. Smiths admits that Plaintiffs' Complaint purports to allege violations of 15 U.S.C. §§ 1, 2, 15, and 26, and denies the remaining allegations in paragraph 12.

13. Smiths admits the allegations in paragraph 13.

14. The allegations in paragraph 14 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 14.

15. The allegations in paragraph 15 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 15.

16. Smiths admits that venue is proper in this District. Smiths denies the remaining allegations in paragraph 16.

BEFORE GENERIC COMPETITION THERE WERE NO RESTRICTIONS ON
THE SALE OR USE OF CARTRIDGES

17. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 17, and accordingly denies all such allegations.

18. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 18, and accordingly denies all such allegations.

19. Smiths admits the allegations in the first two sentences of paragraph 19. Smiths is without knowledge or information sufficient to form a belief as to the truth

of the remaining allegations contained in paragraph 19, and accordingly denies all such remaining allegations.

20. Smiths admits that some PAH patients receive Remodulin subcutaneously using the CADD MS 3 pump but denies the remainder of the allegations in the first sentence of paragraph 20. Smiths denies the allegations in the second sentence of paragraph 20 to the extent that cell phones vary in size. Smiths denies the allegations in the third sentence of paragraph 20 to the extent that it claims that every CADD MS 3 is in consistent operation. Smiths admits the allegations in the last sentence of paragraph 20.

21. Smiths is aware that patients prescribed subcutaneous Remodulin injections by their physicians typically administer their medication using the CADD-MS 3 platform, but lacks knowledge or information sufficient to form a belief as to whether all PAH patients in the United States receiving subcutaneous Remodulin injections use the CADD-MS 3 platform to administer their medication. On that basis, Smiths denies the allegations in paragraph 21.

22. Smiths denies the allegations in paragraph 22 to the extent that there are other pharmacies through which a patient can be prescribed treprostinil, including hospital pharmacies.

23. Smiths admits the allegations in paragraph 23.

24. Smiths admits that prior to Sandoz's March 25, 2019 launch U.S. patients did not have access to a generic version of Remodulin, but denies the remainder of the allegations in paragraph 24.

25. Smiths denies the allegations in paragraph 25.

STATUTORY AND REGULATORY BACKGROUND

26. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 26, and accordingly denies all such allegations.

27. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 27, and accordingly denies all such allegations.

28. Smiths refers to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 ("Hatch-Waxman Act"), for its content and denies any characterization of it.

29. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 29, and accordingly denies all such allegations.

30. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 30, and accordingly denies all such allegations.

31. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 31, and accordingly denies all such allegations.

32. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 32, and accordingly denies all such allegations.

33. Smiths refers to the Hatch-Waxman Act for its content and denies any characterization of it.

UNITED THERAPEUTICS' PLAN TO
"MAKE GENERIC BARBARIC" FAILED

34. Smiths admits the allegations in paragraph 34.

35. Smiths admits the allegations in paragraph 35.

36. Smiths admits the allegations in paragraph 36.

37. Smiths admits the allegations in paragraph 37.

38. Smiths admits the allegations in paragraph 38.

39. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 39, and accordingly denies all such allegations.

40. Smiths admits that United Therapeutics has been developing an implantable Remodulin pump with Medtronic. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 40, and accordingly denies all such additional allegations.

41. Smiths admits that the development of the Medtronic implantable pump took longer than expected. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 41, and accordingly denies all such additional allegations.

42. Smiths admits that United Therapeutics is developing a subcutaneous pump for Remodulin with DEKA. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 42, and accordingly denies all such additional allegations.

43. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 43, and accordingly denies all such allegations.

44. Smiths admits that it is developing the Remolife system with United Therapeutics. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 44, and accordingly denies all such additional allegations,

DEFENDANTS PROHIBIT PATIENTS FROM GAINING
ACCESS TO GENERIC TREPROSTINIL

45. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 45, and accordingly denies all such allegations.

46. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first three sentences Paragraph 46, and accordingly denies all the allegations in those sentences. Smiths denies the allegations in the last sentence of Paragraph 46.

47. Smiths denies the allegations in paragraph 47.

48. Smiths admits that it was not able to fill an order for 300,000 cartridges placed by Raregen, who falsely represented themselves as an affiliate of Accredo. Smiths denies the remaining allegations in paragraph 48.

49. The allegations in paragraph 49 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 49.

50. The allegations in paragraph 50 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 50.

51. Smiths admits that the quote in Paragraph 51 comes from a recent United Therapeutics' 10-K, but denies any characterization of that language. Smiths denies the remaining allegations in paragraph 51.

52. The allegations in the Paragraph 52 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 52.

RELEVANT PRODUCT MARKETS

53. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 53, and accordingly denies all such allegations.

54. Smiths admits the allegations in paragraph 54.

55. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 55, and accordingly denies all such allegations.

56. The first sentence of paragraph 56 of the Complaint sets forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in the first sentence of paragraph 56. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 56, and accordingly denies all such allegations.

57. The allegations in paragraph 57 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 57.

Subcutaneously Injected Treprostinil

58. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 58, and accordingly denies all such allegations.

59. Smiths admits that the language quoted in paragraph 58 comes from a recent 10-K filing by United Therapeutics, but denies any characterization of it. Smiths is without knowledge or information sufficient to form a belief as to the truth

of the remaining allegations contained in paragraph 59, and accordingly denies all such allegations.

60. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 60, and accordingly denies all such allegations.

61. Smiths admits that a physician must prescribe Remodulin injections before a patient can receive the treatment. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in the first two sentences of Paragraph 61, and accordingly denies all such additional allegations. The allegations in the final sentence of Paragraph 61 set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in the final sentences of Paragraph 61.

62. The allegations in paragraph 62 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 62.

Injected Prostacyclins

63. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 63, and accordingly denies all such allegations.

64. Paragraph 64 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 64.

65. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 65, and accordingly denies all such allegations.

66. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 66, and accordingly denies all such allegations.

67. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 67, and accordingly denies all such allegations.

68. The allegations in paragraph 68 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 68.

69. The allegations in paragraph 69 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 69.

RELEVANT GEOGRAPHIC MARKET

70. The allegations in paragraph 70 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 70.

MARKET SHARES

71. Smiths admits that United Therapeutics was the sole provider of subcutaneous treprostinil prior to generic entry. Smiths denies the remaining allegations in paragraph 71 of the Complaint.

72. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 72, and accordingly denies all such allegations.

BARRIERS TO ENTRY

73. The first sentence of paragraph 73 sets forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in that sentence. Smiths is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 73, and accordingly denies all such allegations.

74. Smiths denies the allegations in the first sentence of Paragraph 74. The allegations in the last sentence of Paragraph 74 set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in the last sentence of Paragraph 74.

ANTICOMPETITIVE EFFECTS AND ANTITRUST INJURY

75. Smiths lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 75 of the Complaint. Smiths is aware that patients prescribed subcutaneous Remodulin injections by their physicians typically administer their medication using the CADD-MS 3 platform, but lacks knowledge or information sufficient to form a belief as to whether all PAH patients in the United States receiving subcutaneous Remodulin injections use the CADD-MS 3 platform to administer their medication. On that basis, Smiths denies the remaining allegations in the second sentence of Paragraph 75. The remaining

allegations in paragraph 75 set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the remaining allegations in paragraph 75.

76. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of Paragraph 76, and accordingly denies all such allegations. Smiths denies the remaining allegations in paragraph 76.

77. The allegations in paragraph 77 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 77.

CAUSES OF ACTION

COUNT 1: RESTRAINT OF TRADE (15 U.S.C. § 1)

78. Smiths hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

79. Smiths admits that it entered into a contract with United Therapeutics whereby Smiths would manufacture CADD-MS 3 pumps and cartridges for Remodulin patients. Smiths denies the remaining allegations in paragraph 79.

80. Smiths denies the allegations in paragraph 80.

81. Smiths denies the allegations in paragraph 81.

82. Smiths denies the allegations in paragraph 82.

COUNT 2: MONOPOLIZATION (15 U.S.C. § 2)

83. Smiths hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

84. Smiths admits that it entered into a contract with United Therapeutics whereby Smiths would manufacture CADD-MS 3 pumps and cartridges for Remodulin patients. Smiths denies the remaining allegations in paragraph 84.

85. Smiths denies the allegations in paragraph 85.

86. Smiths denies the allegations in paragraph 86.

87. Smiths denies the allegations in paragraph 87.

COUNT 3: RESTRAINT OF TRADE (N.J. Stat. Ann. § 56:9-3)

88. Smiths hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

89. Smiths admits that it entered into a contract with United Therapeutics whereby Smiths would manufacture CADD-MS 3 pumps and cartridges for Remodulin patients. Smiths denies the remaining allegations in paragraph 89.

90. Smiths denies the allegations in paragraph 90.

91. Smiths denies the allegations in paragraph 91.

COUNT 4: RESTRAINT OF TRADE (N.C. Gen. Stat. § 75-1)

92. Smiths hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

93. Smiths admits that it entered into a contract with United Therapeutics whereby Smiths would manufacture CADD-MS 3 pumps and cartridges for Remodulin patients. Smiths denies the remaining allegations in paragraph 93.

94. Smiths denies the allegations in paragraph 94.

95. Smiths denies the allegations in paragraph 95.

COUNT 5: UNFAIR TRADE PRACTICES (N.C. Gen. Stat. § 75-1.1)

96. Smiths hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

97. Smiths denies the allegations in paragraph 97.

98. The allegations in paragraph 98 of the Complaint set forth legal conclusions to which no answer is required. To the extent an answer is required, Smiths denies the allegations in paragraph 98.

99. Smiths denies the allegations in paragraph 99.

**COUNT 6: TORTIOUS INTERFERENCE WITH PROSPECTIVE
ECONOMIC ADVANTAGE**

100. Smiths hereby incorporates each preceding and succeeding paragraph as though fully stated herein.

101. Smiths is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 101, and accordingly denies all such allegations.

102. Smiths denies the allegations in paragraph 102.

103. Smiths denies the allegations in paragraph 103.

DEMAND FOR JURY TRIAL

104. To the extent an answer is required to Plaintiffs' Demand for Jury Trial, Smiths admits that Plaintiffs purport to ask for a jury trial, but Smiths denies any allegations contained therein and states that Plaintiffs are not entitled to any of the remedies set out in the Complaint.

PRAYER FOR RELIEF

105. To the extent an answer is required to Plaintiffs' Prayer for Relief, the Court has denied Plaintiffs' request for injunctive relief, (ECF No. 169), and Smiths denies any remaining allegations and states that Plaintiffs are not entitled to any of the remedies set out in the Complaint.

AFFIRMATIVE DEFENSES

Smiths asserts the following defenses to the Complaint. Smiths reserves all defenses under Federal Rule of Civil Procedure 8(c) and any other defenses, at law or in equity, that may be available based on discovery and further factual investigation in the case. Smiths further reserves the right to assert any and all defenses on which it does not bear the burden of proof.

FIRST DEFENSE

The Complaint fails, in whole or in part, to state a claim upon which relief may be granted.

SECOND DEFENSE

Plaintiffs' claims are barred, in whole or in part, because some or all Plaintiffs lack standing to bring such claims.

THIRD DEFENSE

Plaintiffs' claims are barred, in whole or in part, because some or all Plaintiffs have not sustained cognizable antitrust injury.

FOURTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Smiths' conduct was not the proximate cause of any damage or injury allegedly suffered by Plaintiffs.

FIFTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the challenged conduct in all material respects enhances competition, benefits consumers,

increases output and supply, and accordingly has caused no injury to competition in any cognizable relevant market.

SIXTH DEFENSE

Any injury to any or all Plaintiffs was or were caused by its or their own acts or omissions, or the acts or omissions of third persons, and not by the actions of Smiths.

SEVENTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs failed to make reasonable efforts to mitigate damages, if any, allegedly suffered as a result of the conduct they allege.

EIGHTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, under the doctrine of *in pari delicto* and/or unclean hands.

NINTH DEFENSE

Smiths incorporates by reference any defenses applicable to it that are asserted by any other defendant to the Complaint as if set forth fully herein.

PRAYER FOR RELIEF

WHEREFORE, Smiths hereby requests that Plaintiffs' Complaint be dismissed in its entirety, with prejudice; that any and all of Plaintiffs' claims for damages or other relief of any sort be denied; that Smiths be awarded costs, disbursements, and reasonable attorneys' fees; and that Smiths be awarded any such other and further relief as this Court may deem just and proper.

Dated: February 12, 2020

KILPATRICK TOWNSEND &
STOCKTON LLP

/s/ Frederick L. Whitmer

Frederick L. Whitmer
The Grace Building
1114 Avenue of the Americas
New York, NY 10036
Telephone: (212) 775-8773
Facsimile: (212) 775-8821
fwhitmer@kilpatricktownsend.com

Peter M. Boyle (*pro hac vice*)
Christina E. Fahmy (*pro hac vice*)
Patrick J. Pascarella (*pro hac vice*)
607 14th Street NW
Washington, DC 20005
Telephone: (202) 508-5800
Facsimile: (202) 585-0057
pboyle@kilpatricktownsend.com
cfahmy@kilpatricktownsend.com
ppascarella@kilpatricktownsend.com

*Attorneys for Defendant Smiths Medical
ASD, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on this 12th day of February, 2020, I electronically filed the forgoing *Smiths Medical ASD, Inc. 's Answer to Complaint* with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all registered CM/ECF users.

/s/ Frederick L. Whitmer
Frederick L. Whitmer